

JUN 12 2002

K020835 1/2

**510(k) Summary
Ceralas Diode Laser System**

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

Biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
Phone: (413) 525-0600
Facsimile: (413) 525-0611

Contact Person: Carol J. Morello, V.M.D.
Date prepared: March 7, 2002

Name of Device and Name/Address of Sponsor

Ceralas Diode Laser System (Model D10-60)
Biolitec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Classification Name

Surgical laser

Predicate Device

Diomed 810nm Surgical Laser
Biolitec Ceralas D10-60 810nm Diode Laser

Intended Use / Indications For Use

In addition to the already cleared indications for use:
For use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

Technological Characteristics

The Ceralas D10-60 Diode Laser and the predicate devices operate with a power range of 1-60W in the CW or pulsed mode.

Substantial Equivalence

The new Ceralas D10-60 has the exact same intended use as the cleared Ceralas D10-60 and the Diomed Laser and the same indications as the combination of Ceralas D10-60 and Diomed Laser. The new Ceralas D10-60 also have the same technological characteristics as the cleared Ceralas D10-60 and very similar technological characteristics as the Diomed Laser. The minor technological differences between the new Ceralas D10-60 and the Diomed Laser raise no new questions of safety or effectiveness. Thus, the new Ceralas D10-60 is substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2002

Biolitec, Inc.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson
555 Thirteenth Street, N. W.
Washington, D.C. 20004-1109

Re: K020835

Trade Name: Ceralas D10-60 810 Diode Laser System and ELVS Procedure Kit
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 27, 2002
Received: March 14, 2002

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

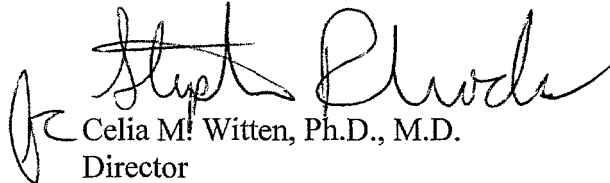
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Jonathan Kahan

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". To the left of the signature is a small, stylized handwritten mark that looks like "JC".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND
D.O.
f/t:410:RFelten:mep:6/11/02

510(k) Number (if known): K020835

Device Name: Ceralas D 10-60 810 nm Diode Laser System

Indications for Use:

In addition to the Ceralas D 10-60 810 nm Diode Laser System's previously-cleared indications, this device is indicated for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K020835

Prescription Use ☒
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)